Special 510(k) SUMMARY
CONTRAST DELIVERY SYSTEM – Dual Shot Alpha 7

DATE SUMMARY PREPARED: June 19, 2013

OFFICIAL CONTACT:

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CLASSIFICATION NAME(S): Angiographic Injector with Syringe

DEVICE CLASSIFICATION: Class II

COMMON NAME: Powered Injector with Syringe

PROPRIETARY NAME: Contrast Delivery System – Dual Shot Alpha 7

PREDICATE DEVICE: Dual Shot Alpha– CONTRAST DELIVERY SYSTEM from NEMOTO KYORINDO K062168 and K071691

INTENDED USE: The contrast delivery system Dual Shot Alpha 7 is an intravascular injection system intended for the administration of ionic and non-ionic contrast media and saline used in conjunction with computed X-ray tomography (CT).

DESCRIPTION OF DEVICE:

The contrast delivery system – Dual Shot Alpha 7 is an angiographic injector that is used in conjunction with Computed Tomography, and is intended for use by doctors, radiology technologists and other licensed medical practitioners. This device is designed to be used in conjunction with various injection methods of contrast media and saline, and utilized with multi-slice CT scanners.

The Dual Shot Alpha 7 has two driving mechanisms to deliver contrast media and/or saline, each side A and B respectively are capable of utilizing either a 100mL or 200mL size syringe. Syringes are connected to the patient via an intravascular catheter. The Dual Shot Alpha 7 consists following components;

- Injector Powerhead
  The injector Powerhead is intended to provide accurate, automatic delivery of contrast media by two electromechanically driven actuators. Sterile empty-syringes or pre-filled syringes can be set onto the Injector head. For the sterile empty-syringes, the injector head provides a Quick Return function to fill the syringe with contrast media or saline. The Powerhead is composed of operation indicator LED, switches for manual operation, start-switch to start infusion and stop-switch to stop infusion. Injector head detects injection conditions and transmits the Injector head status information to the console.

- Console
  The new style Console, now has an integrated power supply with universal voltage input, was designed to take up very little space on a control desk, and consists of TFT LCD display and touch panel interface to set/display various injections set by an operator. The operator can set injection pressure, time, volume, flow rate and a patient examination region of interest. The Dual Shot Alpha 7 also includes as a standard item the Body Weight Protocol from our previous Dual Shot Alpha platform.

- Options

  Hand Switch
  The Hand Switch is connected to the Console and consists of start and stop switches to start/stop injection according to the protocols already set on the console. The Hand Switch provides LED style display to display scan time and injection state.

SUBSTANTIAL EQUIVALENCE:

The contrast delivery system Dual Shot Alpha 7 maintains the same intended use as the predicate device. It is intended for the specific purpose of injecting contrast media and saline solution into a patient's vascular system to obtain diagnostic images in X-ray computed tomography (i.e. "CT").

The contrast delivery system Dual Shot Alpha 7 consists of two main components the Powerhead and Console unlike the predicate device that included an Injector head, a Console, and a Power Supply. Both the Dual Shot Alpha 7 and predicate device consist of the same or substantially equivalent materials and technology. They are motor driven, electromechanical devices that are controlled by software.

Below is a table that compares the predicate device (Dual Shot Alpha) to the proposed modified Dual Shot Alpha 7.

Feature	Proposed Device: Contrast Delivery System – Dual Shot Alpha 7	Predicate Device: Contrast Delivery System – Dual Shot Alpha K062168 and K071691
Intended Use	The contrast delivery system Dual Shot Alpha 7 is an intravascular injection system intended for the administration of ionic and non-ionic contrast media and saline used in conjunction with computed X-ray tomography (CT).	Same
Single or Dual Syringe System	Dual syringe model	Same
Information Display	Color LCD	Same
Programming Keys	Non-dedicated keys – software determined	Same
Touch Screen	Yes	Same
Multi-Phase	1-5 Phases per injection	Same
Interphase Delay	0-300 seconds, 1 sec. increments	Same
Rise Time	Off = 0 seconds, On = 2 seconds	Same
Arming Modes	Single	Same
Protocol Storage Capability	80 protocols	125 protocols
Hold Capability	Until user operate.	Same
Scan Delay	1 – 300 seconds	Same
Variable Jog Speeds	0.5ml/sec, 1.5ml/sec, 8.0ml/sec	Same
Body weight Setting	Yes	Same
Body weight	10~200kg 1kg increment 10~440lb 1lb increment	Same
Contrast media	300, 320, 350, 370, 400 or 3 preset parameter	Same
Iodine volume	10~1000 mgI/kg 1mgI/kg increment	Same
Time	0:01~5:00 or 3 preset parameter	Same
Volume Ratio	5.95~95.5% 1% increment	Same
Injection Results History	100	40
Timing Bolus Duration Mode	Yes	No
Safety Stop Mechanism	Multi layered software stops with backup monitoring.	Same
Syringe System	A-head: 200mL or 100mL syringe B-head: 200mL or 100mL syringe	A-head: 200mL or 100mL syringe B-head: 100mL syringe
Programmed Volume	A or B-head: 1 to 200mL or 1 to 100mL (depending on syringe size)	Same
Volume Remaining Readout	Graphic and numeric on LCD	Same
Flow Rate	0.1mL/sec to 10mL/sec	Same
Programmable Pressure Limit	Settable from 10 to 300PSI	Same
Pause	Programmable – 1 sec to 300 seconds in 1sec increments	Same
Quick Return	Fill rate 0.5, 1.5 and 8.0 mL/sec	Same function different name Auto-Return
Quick Purge	Yes	Yes
Remote Start Switch	Yes	Same
Pressure Graph	Yes	Same
Syringe Sensing	Yes	Same
Test Injection	Yes	Same
Syringe Heat Maintainer	Yes	Same
Power Saver Mode	Yes	No
Integrated Power Supply	Yes	No
Interlocking with CT scanner with NCOM	Yes	Yes
Injection Start	Yes	Yes
Injection Abort	Yes	Yes
Injection Hold	Yes	Yes
Powerhead Indicator lights	Yes	Yes
Power-on Self Test	Yes	Yes
Selectable Injection Patterns	Yes	Yes

PERFORMANCE DATA:

The contrast delivery system Dual Shot Alpha 7 has been tested in conformance with the following recognized standards, and is substantially equivalent to the predicate device Dual Shot Alpha:

EN 60601-1 (2006)	Medical Electrical Equipment, Part 1: General Requirements for basic Safety and essential performance
EN 60601-1-2 (2007)	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6 (2010)	Medical electrical equipment - Part 1-6: General requirements for safety and essential performance - Collateral standard: Usability
EN 62304:2006	Medical Device Software – Software Life Cycle Processes
EN 62366:2008	Medical Devices – Application of usability engineering to medical devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO14971:2012	Medical devices -- Application of risk management to medical devices

Biocompatibility testing has not been performed because the contrast delivery system Dual Shot Alpha 7 does not include a sterile syringe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 30, 2014

Nemoto Kyorindo Co., Ltd.
Ken Wakabayashi
Vice Director
2-27-20 Hongo Bunkyo-ku
Tokyo 113-0033 Japan

Re: K133189
Trade/Device Name: Dual Shot Alpha7
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector with Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: April 4, 2014
Received: June 2, 2014

Dear Ken Wakabayashi,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133189

Device Name: DUAL SHOT alpha7

Indications for Use:

The DUAL SHOT alpha7 is an intravascular injection system intended for the administration of ionic and non-ionic contrast media and saline used in conjunction with computed X-ray tomography (CT).

Prescription Use __O__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner